



DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS-0990-0260-30D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990-0260, which expires on April 30, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to Information.CollectionClearance@hhs.gov or by calling (202) 690-6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, Information.CollectionClearance@hhs.gov or (202) 690-6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990-0260 for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent

Documentation- Extension OMB No. 0990-0260, Assistant Secretary for Health, Office for Human Research Protections.

OMB No.: 0990-0260

Abstract: The information collected through the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/Informed Consent/Consent Documentation collection requirement is the minimum necessary to satisfy the assurance, certification, reporting, disclosure, documentation and recordkeeping requirements of Section 491 (a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR part 46.

Likely Respondents: Research institutions engaged in HHS-conducted or –supported research involving human subjects. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

Total Estimated Annualized Burden – Hours

Title	Number of Respondents	Number of responses per respondent	Average burden per response (in hours)	Total Burden hours
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.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total				1,138,230

Terry S. Clark,
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BILLING CODE 4150-36

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